

MULTICARE™ Control solutions

Levels: Low, Mid, High 3 x 2.5 ml

MULTICARE™ Control solutions must be used to verify the performances in glycaemia (glucose concentration in blood) determinations by MULTICARE system. Solutions contain a known glucose amount which reacts with strip components.

Use. Glucose values ranges of each control solution is indicated in the reagent strip box label. Measurement procedure is similar to the one with blood. In the case you suspect an incorrect functioning of the instrument or of reagent strips, you have to perform a control at least once with each control solution. If you think the measuring result you obtained when measuring your blood sugar is wrong, use the solution which glucose level is nearer as possible to the one you want to control. We recommend to control system accuracy each time you open a new strip packaging. The result you obtain must be within the indicated range on strip packaging. MULTICARE™ control solutions can be used to learn the auto-diagnosis procedure. A correct use of system is confirmed if repeated measurements are inside the range reported in the packaging.

Composition. MULTICARE control solutions contain:

D-glucose in different concentrations, in aqueous solution. Other ingredients (and their approximate concentrations) are indicated here:

Sodium Benzoate	0.2%
Hydrophilic Synthetic Polymer	12.5%
Ponceau Red	0.005%

Principle of the method: Glucose contained in MULTICARE control solutions reacts in a different way from the one contained in blood as it determines different reaction rate and it produces a quite different colour. So, actual glucose concentration in MULTICARE control solution is different from the one indicated in the strip packaging label. MULTICARE control solutions can produce incorrect results if utilised with other determination systems.

Do not use comparative colour card to control system performance when you use MULTICARE when you use control solutions.

Storage and stability. MULTICARE control solutions can be stored at room temperature (15...30°C), even after dropper. At this temperature range a closed dropper is stable until expiry date indicated in the dropper. Once it has been opened, it must be used within 90 days. Write the date of first opening in the space on the label to not use control solution after 90 days since this date. After each use the nozzle should be wiped with a clean, dry and unperformed tissue and the top should be carefully closed.

The bottles and their contents are not hazardous waste and can therefore disposed together with the household refuse.

Procedure. MULTICARE control kit contains control solutions with three different glucose concentration: low- mid- high. Each vial contains 2,5 mL useful for at least 100 measurement.

Required accessories:

- Instrument and e MULTICARE manual
- MULTICARE Strips

Execution

Insert the correct code, indicated on the reactive strips vial you are using, in the MULTICARE instrument. Proceed as for the determination of glucose in blood concentration, using one drop of MULTICARE Control Solution instead of a drop of blood. You will find more detailed information on the instrument user manual. The accuracy of results can be obtained only if you follow very carefully the instructions:

- Avoid air bubbles forming when dosing.
- Apply only one drop in the centre of the strip reactive area.
- The drop must not be sucked back into the bottle if it has already come into contact with the target area.
- The bottle nozzle must not touch the target area of the test strip as this can affect the efficacy of the control solution.

Precautions

1. Use MULTICARE control solutions only for *in vitro* diagnostic.
2. Use this product as it is; do not add any other substance and do not dilute it, otherwise its diagnostic use could be compromised.
3. Do not swallow and do not inject control solutions.

Results which may be expected

At room temperature (15...30°C), 95% of results obtained with MULTICARE control solutions are within the ranges of results given on the labels of Glucoval test strip boxes.

In the case results lie outside the range of results, this may be attributable to the following causes:

- Error in carrying out the control procedure: check procedure again using the user manual, repeat if necessary.
- Expired or contaminated control solution: Use new control solution, if necessary use solutions with other concentrations.
- Expired or contaminated test strips: use new test strips.
- Temperature values too low or too high: carry out at room temperature (15...30°C).
- Instrument problem.

If you obtain no acceptable results:

- **Do not use system to determine glycaemia any longer.**
- **Contact nearest MULTICARE reseller.**

Traceability. Control solutions have been accurately weighed and checked. The corresponding certificates are available for each batch.

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